

ISSUED: 03 July 2018

SAFETY DATA SHEET

Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY

Product Name: **Alfaxan Multidose (alfaxalone 10mg/mL)**

Product Identifier: 10 mg/mL Alfaxalone solution for injection.

Common name / synonyms: Alfaxan Multidose

Product Code: 520510 (10 mL); 520520 (20 mL)

Recommended Use: Intravenous injectable anesthetic for use in cats and dogs.

Restrictions on Use: For veterinary use only. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Importer: Jurox Inc.

Address: American Century Tower II,
4520 Main Street,
Kansas City, MO 64111,
USA

Emergency telephone number: 1-844-253-2926

Customer Centre: 1-844-253-2926

Poison help line: 1-800-222-1222 (AAPCC 24 hour hotline)

Section 2: HAZARDS IDENTIFICATION

GHS Hazard Classifications: This product has been assessed according to GHS and is classified as follows:

GHS Category	Hazard code	Hazard Statement
Flammable Liquid Category 3	H226	Flammable liquid and vapor
Eye Irritant Category 2A	H319	Causes serious eye irritation

Signal Word: **WARNING**

GHS Pictograms:



Flame



Exclamation Mark

GHS Precautionary Statements:

Prevention

P210 Keep away from heat / sparks / open flames / hot surfaces – No smoking.

P233 Keep container tightly closed.

P240 Ground and bond container and receiving equipment.

P241 Use explosion-proof electrical/ventilating/lighting/intrinsically safe equipment.

P242 Use only non-sparking tools.

P243 Take precautionary measures against static discharge.

P264 Wash hands thoroughly after handling.

P280 Wear protective gloves / eye protection / face protection.

Response

P370 + P378 In case of fire: Use water spray / fog for extinction.

P303 + P361 + P353 IF ON SKIN (or hair): Remove / Take off immediately all contaminated clothing. Rinse skin with water / shower.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337 + P313 If eye irritation persists: Get medical advice/attention

Storage

P403 + P235 Store in a well-ventilated place. Keep cool.

Disposal

P501 Dispose of unused product in accordance with local regulations. Dispose of empty container by wrapping with paper and placing in garbage. Discarded needles should immediately be placed in a designated and appropriately labelled 'sharps' container.

Description of any hazards not otherwise classified identified during the classification process:

Possible sedation or anaesthesia on self-injection.

Short term: May cause drowsiness, dizziness, respiratory depression and unconsciousness. May cause eye irritation.

Long term: May cause damage to the liver and cause scarring (based on ingredients).

Ingredient(s) with unknown Toxicity:

None.

Section 3: COMPOSITION / INFORMATION on INGREDIENTS

INGREDIENT	CAS No.	GHS Classification	CONTENT
Alfaxalone	23930-19-0	Non-hazardous	1%
Ethanol	64-17-5	Eye Irritant Category 2A, Flammable Liquid Category 2	10 – 30%
Chlorocresol	59 -50-7	Skin Sensitizer Category 1	<1%
Ingredients not contributing to hazards	-	-	> 60%

- There are no impurities or stabilizing additives which are themselves classified and which contribute to the classification of the substance.
- Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200 – Hazard Communication, the exact percentage composition of this mixture has been withheld as a trade secret.

Section 4: FIRST AID MEASURES

First aid measures: Consult the Poisons Help Line on 1-800-222-1222 or a doctor immediately in every case of suspected chemical poisoning. Never give fluids or induce vomiting if a patient is unconscious or convulsing regardless of cause of injury. If medical advice/attention is needed, have this SDS, product container or label at hand.

Inhalation: If respiratory symptoms occur, remove patient to fresh air. Lay patient down and keep warm and rested. If breathing is shallow or has stopped, ensure airway is clear and apply resuscitation. If breathing is difficult, give oxygen. Seek medical assistance immediately.

Ingestion: If swallowed, DO NOT induce vomiting. Rinse mouth. Keep subject warm and at rest. For advice, contact the Poisons Help Line on 1-800-222-1222.

Skin: If skin contact occurs, wash affected area thoroughly with plenty of soap and water for at least 20 minutes. If skin irritation or rash occurs, get medical advice/attention.

Eye: If eye contact occurs, rinse cautiously with water for at least 20 minutes. Continue rinsing. If eye irritation persists, get medical advice/attention.

Injection: Treat as for needle stick injury. Wash the wound thoroughly with soap and water or use a waterless cleanser or antiseptic if water is unavailable. Apply a dressing as necessary, and apply pressure through the dressing if bleeding is still occurring. Do not squeeze or rub the injury site. Dispose of the needle in a suitable sharps container and seek medical advice/attention immediately.

Recommended First Aid Facilities: Ready access to running water and soap is required. Accessible eyewash is required.

Advice to Doctor: Treat symptomatically.

Section 5: FIRE FIGHTING MEASURES

Extinguishing Media: Foam, dry chemical powder, BCF (where regulations permit), carbon dioxide, water spray or fog (Large fires only).

Hazardous Combustion Products: Flammable liquid. Moderate fire hazard when exposed to heat or flame. Combustion products include carbon monoxide, carbon dioxide and other pyrolysis products typical of burning organic material.

Flash Point: 43.5 °C.

Protective Equipment: For bulk product: Safety glasses with side shields / chemical goggles. Chemical protective gloves e.g. PVC. Safety footwear or safety gumboots e.g. rubber. Overalls / PVC apron – PVC protective suit may be required if exposure severe. Respiratory protection – Type A filter of sufficient capacity. Eyewash unit. Ready access to a safety shower.

Section 6: ACCIDENTAL RELEASE MEASURES

Spills and Disposal: Wear appropriate protective clothing. For small spills (i.e. those associated with normal use of the product), wipe up spill with paper towels or other suitable materials. Rinse area with water. For large spills, exclude non-essential people from the area. Contain spill and absorb with inert material such as soil, sand or absorbent granules and place in a sealable waste container. Ventilate area and wash spill site after pick-up complete. Dispose of waste safely in an approved landfill.

Protective Clothing: For appropriate personal protective equipment see section 8.

Environmental Precautions: Prevent from entering drains, waterways or sewers. If contamination of drains and waterways occurs, advise local authority.

Section 7: HANDLING AND STORAGE

Handling: This is a Controlled Drug (Schedule IV) with federal law restricting this drug to use by or on the order of a licensed veterinarian. Prescribing practitioners must adhere to the laws and regulations of the FDA, DEA, the States in which they are practising and their licencing boards. In the event that discrepancies between Federal and State laws exist the more stringent of the two must be followed.

Do not eat, drink, smoke or apply cosmetics while handling the product. Wash hands thoroughly after handling.

Avoid accidental injection, ingestion, inhalation and contact with skin and eyes. Use personal protective equipment as required.

Storage: Store at controlled room temperature 20°C - 25°C (68° to 77°F) with excursions between 15° and 30°C (59° and 86°F). ALFAXAN MULTIDOSE contains preservatives. The product can be used for 28 days after broaching the vial. Any unused ALFAXAN MULTIDOSE remaining after 28 days should be discarded.

No known incompatibilities for storage.

Other Information: Always read the label before use. See label for further information on handling and storage.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Limits: No exposure limits have been assigned for the manufactured product. Use with adequate ventilation. Follow standard veterinary product handling procedures.

Do not handle until all safety precautions have been read and understood. Due to the small volumes involved, and the methods of administration, exposure under normal conditions of use would likely be limited to splashing on to skin or in to eyes, or accidental self-injection.

Exposure limits for the major components are as follows:-Occupational Exposure Limits (OEL)

Component	Exposure		
	Type	TWA mg/m ³	STEL ppm
Alfaxalone	US NIOSH Recommended Exposure Limits (RELs)	NE	NE
Alfaxalone	US ACGIH Threshold Limit Values (TLV)	NE	NE
Alfaxalone	US OSHA Permissible Exposure Levels (PELs)	NE	NE
Ethanol	US NIOSH Recommended Exposure Limits (RELs)	1000 ppm / 1900 mg/m ³	NE
Ethanol	US ACGIH Threshold Limit Values (TLV)	NE	1000 ppm
Ethanol	US OSHA Permissible Exposure Levels (PELs)	1000 ppm / 1900 mg/m ³	NE
Chlorocresol	US NIOSH Recommended Exposure Limits (RELs)	0.5 mg/m ³	NE
Chlorocresol	US ACGIH Threshold Limit Values (TLV)	0.5 mg/m ³	NE
Chlorocresol	US OSHA Permissible Exposure Levels (PELs)	0.5 mg/m ³	NE

NE – Not established.

Emergency Limits:

Component	TEEL-1	TEEL-2	TEEL-3
Chlorocresol	5.5 mg/m ³	60 mg/m ³	360 mg/m ³

Engineering Controls: Use only in a well ventilated area. Ensure that the work environment remains clean.

Protective Equipment (PPE):

Hands: Chemical protective gloves

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Wear protective clothing when working with large quantities.

Respiratory Protection: Not required for the normal use of this product.

Hygiene precautions: As for good veterinary practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Clear, colourless liquid	Upper / Lower Flammability Limits	Not available.
Odour	Not available.	Vapour Pressure	Not available.
Odour Threshold	Not available.	Vapour Density	Not available.
pH	Approx. 7	Relative Density / Specific Gravity	1.01
Melting Point / Freezing Point	Not available.	Solubility	Miscible in water.
Boiling Point and Boiling Range	Not available.	Partition Coefficient (n-octanol/water)	Not available.
Flash Point	43.5°C	Auto-Ignition Temperature	Not available.
Evaporation Rate	Not available.	Decomposition Temperature	Not available.
Flammability	Flammable	Viscosity	Not available.

Section 10: STABILITY AND REACTIVITY

Reactivity: May react with oxidizing agents.

Chemical Stability: Stable under normal conditions of storage and handling. When stored appropriately this product should show no significant degradation before the expiry date indicated on the packaging. Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerisation will not occur.

Possibility of hazardous reactions: Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result.

Conditions to Avoid: Keep away from heat, spark, flames and all other sources of ignition. Avoid prolonged exposure to higher temperatures and/or direct sunlight.

Incompatible Materials: Oxidising agents.

Hazardous Decomposition Products: Heating may cause expansion or decomposition leading to violent rupture of containers. Combustion products include carbon monoxide, carbon dioxide, other pyrolysis products typical of burning organic material.

Section 11: TOXICOLOGICAL INFORMATION

General Information: Toxicological properties of the formulation have not been investigated. The information in this Section describes the potential hazards of the individual ingredients and the formulation.

Inhalation: Inhalation of vapours may cause drowsiness and dizziness. This may be accompanied by sleepiness, reduced alertness, loss of reflexes, lack of co-ordination, and vertigo. Animal testing shows that the most common signs of inhalation overdose are inco-ordination and drowsiness.

Ethanol: Inhalation (rat) LC₅₀: 63926.976 mg/L/4h

Ingestion: Ingestion of ethanol (ethyl alcohol, "alcohol") may produce nausea, vomiting, bleeding from the digestive tract, abdominal pain, and diarrhoea.

Ethanol: Oral (rat) LD₅₀: 7060 mg/kg

Alfaxalone: Oral (rat) LD₅₀: 297 mg/kg

Skin: Not a skin irritant. However, open cuts, abraded or irritated skin should not be exposed to this material. Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects.

Alfaxalone: Skin (rat) LD₅₀: 2,200 mg/kg

Serious Eye Damage / Irritation: Based on available data for the ingredients, the mixture is considered to be an **Eye Irritant Category 2A**.

Ethanol: Eye (rabbit): 500 mg - Severe irritation, 100 mg / 24 hr - Moderate irritation

Injection: Alfaxalone is an anaesthetic. Avoid needle stick injury. The product will cause drowsiness, dizziness or anaesthesia.

Alfaxalone: Intravenous LD₅₀: 19 mg/kg (rat)

Chronic Effects: No adverse effects were reported from intraperitoneal administration of alfaxalone to rats of up to 50 mg/kg/day for one month, or up to 20 mg/kg/day for 3 months. However, prolonged exposure to ethanol may cause damage to the liver and cause scarring. It may also worsen damage caused by other agents.

Reproductive Toxicity: Not known to affect reproduction. Studies using alfaxalone in pregnant mice, rats and rabbits have demonstrated no deleterious effects on gestation of the treated animals or on the reproductive performance of their offspring.

Mutagenicity: Alfaxalone is not considered to be mutagenic.

Carcinogenicity: There are no reports of the carcinogenicity of Alfaxan in animals in published literature or pharmacovigilance data, and no pre-neoplastic lesions were observed in repeat dose toxicity or target species safety studies. Alfaxalone is classified in Group 3 (Not classifiable as to its carcinogenicity to humans) in the IARC Monographs. Alfaxalone has not been reviewed in NTP Reports on Carcinogens.

Section 12: ECOLOGICAL INFORMATION

Aquatic toxicity: Not determined for product.

Alfaxalone: No data available.

Ethanol: LC₅₀ (96 hr) (fish): 42 mg/L

EC₅₀ (48 hr) (crustacea): 2 mg/L

EC₅₀ (96 hr) (algae / aquatic plants): 17.921 mg/L

NOEC (2016 hr) (fish): 0.000375 mg/L

Chlorocresol: LC₅₀ (96 hr) (fish): 0.971 mg/L
EC₅₀ (48 hr) (crustacea): 1.5 mg/L

Persistence / Biodegradability: Not determined for product.

Alfaxalone: No data available.
Ethanol: Water/soil: LOW (Half-life = 2.17 days)
Air: LOW (Half-life = 5.08 days)
Chlorocresol: Water/soil: LOW (Half-life = 49 days)
Air: LOW (Half-life = 0.67 days)

Bioaccumulation: Not determined for product.

Alfaxalone: No data available.
Ethanol: LOW (LogKOW = -0.31)
Chlorocresol: LOW (BCF = 13)

Mobility in soil: Not determined for product.

Alfaxalone: No data available.
Ethanol: HIGH (KOC = 1)
Chlorocresol: LOW (KOC = 717.6)

Section 13: DISPOSAL INFORMATION

Product Disposal: All waste materials must be properly characterized. Further, disposal should be performed in accordance with federal, state and local regulatory requirements.

Container Disposal: Dispose of container and unused contents in accordance with federal, state and local regulations.

Section 14: TRANSPORT INFORMATION

Labels Required:

DG label:	
Marine Pollutant	No

Land transport (DOT)

UN number	1170				
UN proper shipping name	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)				
Transport hazard class(es)	<table border="1"> <tr> <td>Class</td><td>3</td></tr> <tr> <td>Subrisk</td><td>Not applicable</td></tr> </table>	Class	3	Subrisk	Not applicable
Class	3				
Subrisk	Not applicable				
Packing group	III				
Environmental hazard	Not Applicable				
Special precautions for user	<table border="1"> <tr> <td>Hazard Label</td><td>3</td></tr> <tr> <td>Special provisions</td><td>24, B1, IB3, T2, TP1</td></tr> </table>	Hazard Label	3	Special provisions	24, B1, IB3, T2, TP1
Hazard Label	3				
Special provisions	24, B1, IB3, T2, TP1				

Air transport (ICAO-IATA / DGR)

UN number	1170	
UN proper shipping name	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)	
Transport hazard class(es)	▪ ICAO/IATA Class	3
	▪ ICAO / IATA Subrisk	Not applicable
	▪ ERG Code	3L
Packing group	III	
Environmental hazard	Not Applicable	
Special precautions for user	▪ Special provisions*	A3 A58 A180
	▪ Cargo Only Packing Instructions	366
	▪ Cargo Only Maximum Qty / Pack	220 L
	▪ Passenger and Cargo Packing Instructions	355
	▪ Passenger and Cargo Maximum Qty / Pack	60 L
	▪ Passenger and Cargo Limited Quantity Packing Instructions	Y344
	▪ Passenger and Cargo Limited Maximum Qty / Pack	10 L

* Under special provisions A3, A58 (144), A180 of the Technical Instructions for the safe transport of dangerous goods by air, an aqueous solution containing not more than 24% alcohol by volume is not subject to these instructions. Therefore not regulated for air transport under IATA regulations.

Sea transport (IMDG-Code / GGVSee)

UN number	1170	
UN proper shipping name	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)	
Transport hazard class(es)	▪ IMDG Class	3
	▪ IMDG Subrisk	Not applicable
Packing group	III	
Environmental hazard	Not Applicable	
Special precautions for user	▪ EMS Number	F-E , S-D
	▪ Special provisions*	144 223
	▪ Limited Quantities	5 L

* Under special provisions 144, 223 of the Chapter 3.3 of the IMDG Code, an aqueous solution containing not more than 24% alcohol by volume is not subject to the provisions of this Code. Therefore not regulated for sea transport under IMDG regulations.

Transport in bulk according to Annex II of MARPOL and the IBC code

Component	Pollution Category	Ship Type
Ethanol	Z	Not applicable

Section 15: REGULATORY INFORMATION

FDA Approval:	NADA 141-342
Harmonised Tariff Code:	304.90.9103
TSCA Inventory Status:	Exempt
CERCLA Status:	Not determined
RCRA Status:	Not an RCRA Hazardous Waste
Proposition 65 Status:	Does not contain chemicals known to the state of California to cause cancer or reproductive harm.
USA Regulations:	

Substance	SARA 302 Status	SARA 304	SARA 313 Status	PROP 65 Status
Alfaxalone	Not listed	Not listed	Not listed	Not listed

Canadian Regulations:

Canadian Inventory:	Not determined.
Canadian NDSL:	Not determined.
WHMIS Hazard Class:	Not determined.

Section 16: OTHER INFORMATION

Legend:

AAPCC	American Association of Poison Control Centres
ACGIH	American Conference of Governmental Industrial Hygienists
ADG	Australian Dangerous Goods Code
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
BCF	Bromochlorodifluoromethane
BCF	Bio Concentration Factor
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation and Liability Act
DOT	US Department of Transport regulations
EC ₅₀	The median effect concentration, being a statistically derived concentration of a substance that can be expected to cause an adverse reaction in 50% of organisms or a 50% reduction in growth or in the growth rate of organisms
EMS Number	EMS = Emergency Response Procedures for Ships Carrying Dangerous Goods. EMS codes are assigned to each UN Number in column 15 of the Dangerous Goods List in IMDG Code Chapter 3.2.
EPA	US Environmental Protection Agency
ERG Code	ERG = Emergency Response Guidebook: A Guidebook for First Responders During the Initial Phase of a Dangerous Goods / Hazardous Materials Transportation Incident. This contains hazard identification codes.
FDA	Food and Drug Administration, US Dept. of Health and Human Services
GGV/See	Transport of Dangerous Goods by Sea Ordinance
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HCS	Hazard Communication Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IBC Code	International Bulk Chemical Code
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods Code
KOC	Soil-Water Partition Coefficient. The ratio of a chemical's concentration that is adsorbed in the soil to the concentration of chemical in solution
KOW	Octanol Water Partition Coefficient. The ratio of a compound's concentration in a known volume of n-octanol to its concentration in a known volume of water after the octanol and water have reached equilibrium
LC ₅₀	The median lethal concentration, being a statistically derived concentration of a substance that can be expected to cause death in 50% of animals
LD ₅₀	The median lethal dose, being a statistically derived single dose of a substance that can be expected to cause death in 50% of animals

MARPOL 73/78	International Convention for the Prevention of Pollution from Ships, 1973 as modified by the Protocol of 1978
NADA	New Animal Drug Application
NDSL	Non-Domestic Substances List
NOEC	No Observed Effect Concentration
NTP	National Toxicology Program
OSHA	Occupational Safety & Health Administration (United States Department of Labor)
OEL	Occupational Exposure Limits
PEL	Permissible Exposure Limit
PPE	Personal Protective Equipment
Prop 65	California Proposition 65
PVC	Polyvinyl chloride
RCRA	US EPA, Resource Conservation and Recovery Act
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short term exposure limit
TEELs	Temporary Emergency Exposure Limits. Guidelines designed to predict the response of members of the general public to different concentrations of a chemical during an emergency response incident
TEEL-1	The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic, nonsensory effects. However, these effects are not disabling and are transient and reversible upon cessation of exposure
TEEL-2	The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting, adverse health effects or an impaired ability to escape.
TEEL-3	The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience life-threatening adverse health effects or death
TSCA	Toxic Substance Control Act
TLV	Threshold Limit Value
TWA	Time-Weighted Average. The average exposure over a specified period, usually a nominal eight hours
UN	United Nations
VMD	United Kingdom Veterinary Medicines Directorate
VSD	Veterinary Substances Database
WHMIS	Canadian Workplace Hazardous Materials Information System

References:

Summary of Product Characteristics (SPC) of Alfaxan Multidose 10 mg/mL solution for injection for dogs, cats and pet rabbits. www.vmd.defra.gov.uk/productinformationdatabase/SPC.../SPC_1365063.DOC

Veterinary Substances Data Base (VSDB) entry on Alphaxalone
(<http://sitem.herts.ac.uk/aeru/vsdb/Reports/1759.htm>)

This version issued: 03 July 2018. The format follows that prescribed in the Hazard Communication Standard (HCS) (29 CFR 1910.1200(g)) revised in 2012.

Supersedes: This is the first SDS for this product.

Revision History:

Date of Revision	Reason

This information is based on data believed by the manufacturer Jurox Pty Limited to be accurate at the time of writing but is subject to change without notice. It is given in good faith, but no warranty expressed or implied is made as to its accuracy, completeness otherwise and no assumption of liability from whosoever arising is made by Jurox Pty Limited by reason of the provision of this information. Every person dealing with the materials referred to herein do so at his/her own risk absolutely and must make independent determinations of suitability and completeness of information from all sources to ensure their proper use.

END OF SDS